



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,042	04/21/2004	Trevor Barrowcliffe	674583-2001	7419
20999	7590	06/29/2005	EXAMINER	
FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151			ROOKE, AGNES BEATA	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 06/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding..

Office Action Summary	Application No. 10/829,042	Applicant(s) BARROWCLIFFE, TREVOR	
	Examiner Agnes B Rooke	Art Unit 1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 13-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>04/29/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This final action is in response to the Applicant's reply filed on March 22, 2005.

The amendments to the claims filed on March 22, 2005 have been acknowledged.

Claims 1, 2, and 5 have been amended.

Claims 9-12, 16, and 17 have been withdrawn.

Claims 1-8 and 13-15 are currently under examination.

Any objection or rejection not specifically restated herein is withdrawn.

Rejections Maintained

35 USC § 112, second paragraph

Rejection to Claim 1 is maintained under 35 U.S.C. 112, first paragraph.

In the first office action examiner stated that in Claim 1 it is not definite whether the claimed composition contains: 1) only FIX; 2) only FVIII; or 3) both FIX and FVIII together as thus the claim being interpreted as three separate inventions.

Applicant responded that Claim 1 relates to two separate compositions, the first comprising FIXa and the second comprising FVIII.

Examiner disagrees because Claim 1, reads "A composition comprising a coagulation factor IXa and a composition comprising a coagulation factor VIII..." Thus, one composition does not exclude the other and there is no mention in the claim that only two separate compositions are claimed. Therefore, the rejection is maintained

Art Unit: 1653

since examiner interprets claim 1 as having one composition with factors VIII and IXa together and/or two compositions, the first with coagulation factor VIII and second with only coagulation factor IXa. Therefore, to clarify Claim 1, Applicant should state clearly and unambiguously that claim 1 relates to two compositions only, the first comprising coagulation factor IXa and the second comprising a coagulation factor VIII. Further, Claim 2, which depends from Claim 1 states : "A method of using a coagulation factor IXa and a coagulation factor VIII in the preparation of a composition according to claim 1.." Thus, examiner interprets Claim one as having one composition with factors IXa and VIII together and/or two compositions where one has factor IXa only and the second has factor VIII only.

Rejection to Claims 4 and 13 are maintained, since the Applicant did not spell out the full name of the coagulation factor IXa and coagulation factor VIII as suggested in the first office action.

New Rejection

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1, 2, 4-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite since there is nothing linking these two compositions, such as a kit comprising these two compositions, for example.

Claim 2 refers to a term "admixing" which does not explain with a clarity how to use the invention "in the preparation of a composition of claim 1." Examiner suggests a wording, for example, "A method of making a composition comprising coagulation factor IXa and VIII according to claim 1 for the treatment of haemophilia A or haemophilia B in a subject who does not present with anti-coagulation factor VIII."

Claims 4-8 lack method steps related to using factor IXa in the manufacture of a composition comprising factor VIII. Claim 5 has a method step but administering has nothing to do with manufacturing the composition.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3 are rejected under 35 U.S.C. 101 because they refer to a product of nature, since claimed coagulation factors are not isolated or purified.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1-3 are rejected under 35 U.S.C. 102(a) over non-haemphiliac human blood. Non-haemophiliac human blood has both factor IXa and factor VIII as well as some phospholipids. Since "comprising" is non-limiting the above claims are anticipated.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 and 13-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Lang et al. (U.S. 5,506,112).

Lang et al. teach a method where a mixture of factor IXa, and phospholipids is added to a factor VIII-containing sample, thus activating factor VIII to be assayed; and where subsequently activated factor VIII forms complex with factor IXa. See column 1, lines 8-14.

Claims 14 and 15 are included in this rejection because they depend from rejected independent claim 13.

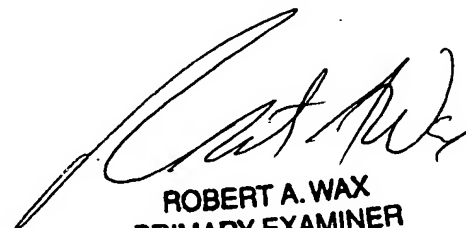
Conclusion

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-273-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

AR


ROBERT A. WAX
PRIMARY EXAMINER
Art Unit 1653